EXHIBIT G

References: 1. N Engl J Med. 2003;348(10):900–7
2. Int Urogynecol J. 2015 DOI 10.1007/s 00192-015-2916-1
3. Obstet Gynecol. 2015;125(3):531–9

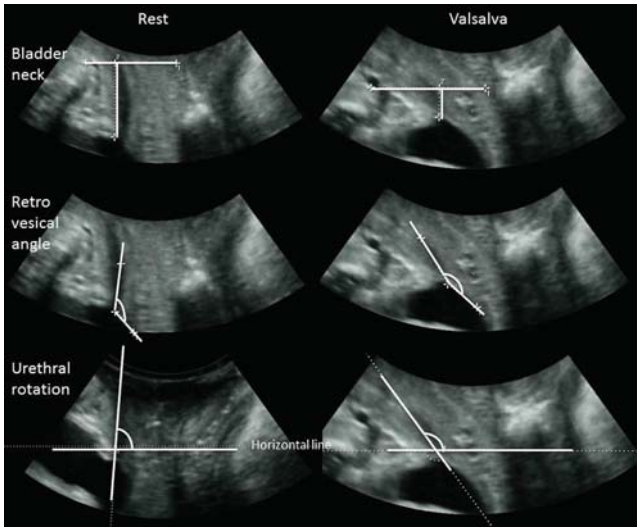

Table 1

	Variable	Group	Antenatal N=180	1 year pp N=147	4 years pp N=147	Significant differences over time
UI symptoms	ICIQ-SF score (range 0-24) Mean (SD)	≥1 CS	3.7 (4.8)	2.9 (4.5)	3.8 (5.2)	Antenatal to 1y (p=0.27) Antenatal to 4 y (p=0.34) 1y to 4y (p=0.04)
		≥1 VD LAM intact	3.0 (3.8)	2.7 (3.4)	3.7 (4.2)	
		≥1 VD LAM avulsion	3.1 (3.5)	3.1 (3.2)	3.2 (3.9)	
Bladder neck and urethral mobility	Bladder neck descent (cm) Mean (SD)	≥1 CS	1.0 (0.9)	1.0 (0.8)	1.2 (0.6)	Antenatal to 1y (p=0.22) Antenatal to 4y (p=<0.01) 1 y to 4y (p=<0.01)
		≥1 VD LAM intact	0.9 (0.7)	1.1 (0.8)	1.3 (1.2)	
		≥1 VD LAM avulsion	1.0 (0.7)	1.1 (0.6)	1.8 (0.8)	
	Urethral rotation (degrees) Mean (SD)	≥1 CS	25 (23)	33 (23)	40 (21)	Antenatal to 1y (p<0.01) Antenatal to 4 y (p<0.01) 1 y to 4y (p=0.046)
		≥1 VD LAM intact	23 (17)	38 (22)	42 (24)	
		≥1 VD LAM avulsion	26 (18)	46 (21)	47 (25)	
	Retro vesical angle at Valsalva (degrees) Mean (SD)	≥1 CS	149 (25)	139 (30)	152(31)	Antenatal to 1y (p=0.32) Antenatal to 4y (p=0.02) 1 y to 4y (p=<0.01)
		≥1 VD LAM intact	146 (23)	148 (28)	160 (27)	
		≥1 VD LAM avulsion	148(19)	146 (37)	155 (30)	

PP 19

THE MYTH: IN VIVO DEGRADATION OF POLYPROPYLENE MESHES

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Abstract:

Introduction: Use of polypropylene (PP) hernia and urogynecological meshes began in the 1960s. Some have recently observed cracked surfaces on explanted meshes and proposed those as degraded PP, without considering the formalin fixation process and inadequate mesh cleaning.

Objective: Analyze morphology and material chemistry of explanted Prolene meshes via a novel, effective, cleaning process.

Methods: Explanted Prolene meshes were cleaned using distilled water (to reverse the well-known chemistry of the fixative crosslinking reaction), sodium hypochlorite and Proteinase K. At each intermediate cleaning step, analysis included Light Microscopy, Fourier Transform Infrared Spectroscopy, and Scanning Electron Microscopy.

Results: Identical translucent and sometimes clear cracked/flaking material on blue and clear fibers was observed (Fig. 1).

Fig. 1: Had Prolene been oxidized, *in vivo* blue fiber flakes would be blue and clear fiber flakes would be clear, instead of identical translucent/sometimes clear cracked and flaking material and both blue and clear fibers.

Had Prolene been oxidized, blue fiber flakes would be blue and clear fiber flakes would be clear. Cleaning progressively removed bulk tissue and regions with cracked material on the explant surfaces, exposing clean, smooth, unoxidized and non-degraded fibers with no visible gradient-type, ductile damage, which would have occurred if Prolene degraded in vivo (Fig. 2).

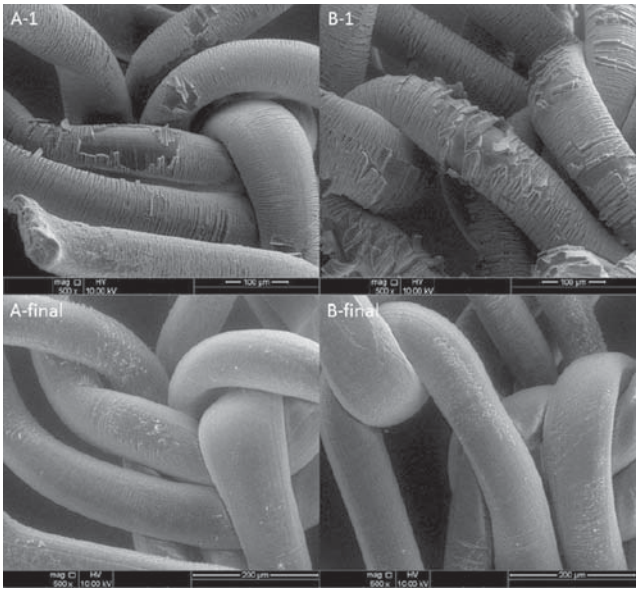

Fig. 2: SEM images showing progressive removal of cracked material at two locations (A and B) on explanted Prolene mesh after bulk tissue removal (A-1, B-1) and after progressive cleaning (A-final, B-final).

EDS showed magnesium, phosphorus, and calcium, etc. in cracked regions, but not in non-cracked regions or exemplar fibers. These are elements common to biological matter. FTIR of explants spectrally absorbed at ~1740 cm-1, which others have stated as consistent with oxidative degradation. However, this absorption represents a Prolene antioxidant. An absorption frequency of 1650 cm-1 is attributed to byproducts of oxidative degradation, but is within protein's absorption region and expected to be present. FTIR confirmed progressive protein removal and loss of protein absorption intensity after each cleaning step (Fig. 3).

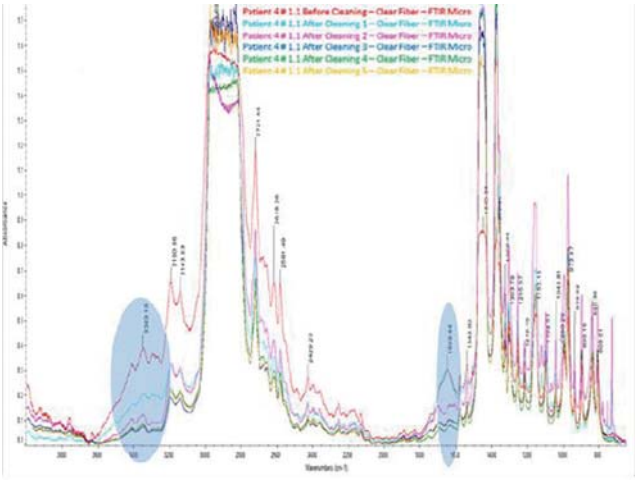

Fig. 3: FTIR showing progressive loss of adsorbed protein coating with cleaning.

Conclusions: Explanted Prolene meshes did not undergo meaningful or harmful degradation in vivo. Instead, the cracked layer was composed of adsorbed protein coating arising from a well-established phenomenon occurring immediately upon implantation in vivo. Adsorbed proteins when placed in formalin fixative begin immediately to crosslink and forms a hard, brittle, protective composite layer.

References: n/a

PP 20

MOLECULAR EFFECTS OF INTRAVENOUS MUSCLE-DERIVED STEM CELLS THERAPY IN THE DAMAGED URETHRAL TISSUE OF FEMALE RATS: GENE AND PROTEIN EXPRESSION PROFILE.

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Abstract:

Introduction: Stress urinary incontinence (SUI) is a high prevalent condition in women.

Cell therapy has been considered as a promising therapy for SUI. Since muscle-derived stem cells (MDSC) can be obtained easily in large quantities, these cells may exhibit advantages in cell therapy applications in patients with SUI.

Objective: Our aims were to analyze the effects of MDSC intravenous injection in the urethra of rats after trauma by vaginal distention and compare them with controls and traumatized rats without treatment in regards to: (1) mRNA expression of collagens, vascular endothelial growth factor A (VEGF), nerve growth factor (NGF), Ki67 cell proliferation marker, and the expression of genes related to smooth and striated muscle apparatus; (2) expression of smooth and striated muscle proteins.

Methods: We investigated the urethras of three groups of rats: control, animals subjected to a 12-h intermittent vaginal distention only (VD) and that received MDSC therapy (VD+MDSC). MDSC were obtained from mutant rats expressing green fluorescent protein (GFP), and further cultivated in vitro. MDSC were injected into the tail vein of the rats at day 3 after VD and the urethras were analyzed at day 28.

We used real-time RT-PCR methodology for gene expression profile: Skeletal muscle myosin heavy chain (Myh1), Smooth muscle myosin heavy chain (Myh11), Ki67, Collagen type I (COL1), Collagen type III (COL3), VEGF and NGF.

We used Immunohistochemistry for identification and quantification of Myh11 and Myh1 proteins. The image analysis software HistoQuant (3DHISTECH) was used to selected immunopositive areas and obtain the value of the area marked in relation to the total area of each urethra.

Kruskal-Wallis test (Dunn's post-test) and ANOVA test (Tukey's post-test) were used for statistical analysis, with $p<0.05$ for significance.

Results: At 4 weeks after VD, Ki-67, COL1 and COL3 genes expression were significantly upregulated in VD+MDSC group compared to controls ($p=0.01$, $p=0.008$, $p=0.03$, respectively). In addition, Ki-67 and COL1 genes were overexpressed in VD+MDSC group compared to VD ($p=0.02$, $p=0.03$, respectively) (Fig. 1).

On the other hand, NGF mRNA expression was significantly downregulated after VD+MDSC compared to VD group ($p=0.002$). VEGF gene expression was not different among the groups (Fig. 1).

Myh11 and Myh1 genes were overexpressed in VD group in relation to control ($p=0.03$ and $p=0.04$, respectively) with no